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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/718,504

11/19/2003

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EXAMINER

RYCKMAN, MELISSA K

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/718,504	<b>Applicant(s)</b> EPSTEIN ET AL.	
	<b>Examiner</b> MELISSA RYCKMAN	<b>Art Unit</b> 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 19,21-26 and 28-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19,21-26 and 28-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/2/08</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/22/08 has been entered.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19, 26 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Khairkhan et al. (US 2002/0111647).

Regarding Claim 19, Khairkhan teaches an expandable device for use in a body lumen or tract, the device comprising: a tubular member (16) having a proximal end and a distal end; a first expandable member (11) disposed on the distal end of the tubular member, the first expandable member having a contracted configuration and an expanded configuration, wherein the first expandable member (11) comprises a single wire (Fig. 7, distal portion of 218 is the wire) that can be shifted between a straightened

(when unexpanded the wire is straight) contracted configuration and a helical expanded configuration (Fig 7, 218 forms a helix); a first deformable membrane (15) at least partially disposed over the first expansible member in the expanded configuration (fig. 1); a second expansible member (194) disposed proximal the first expansible member on a distal end of the tubular member, the second expansible member having a contracted configuration and an expanded configuration; wherein the first deformable membrane has a spherical shape (Figs. 7-10) when the first expansible member is in the expanded configuration and the second expansible member has a cylindrical shape in the expanded configuration (a portion of 218 is cylindrical).

Regarding Claim 27, Khairkhan teaches the device of claim 19, wherein the first deformable membrane comprises a spherical shape when the first expansible member is in the expanded configuration (fig. 1).

Regarding Claim 28, Khairkhan teaches a reference stop (distal portion of 195 is a reference stop) disposed between the first deformable membrane (15) and the distal end of the tubular member (16).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 19, 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Latson et al. (US 5861003) and further in view of Khairkhahan et al. (US 2002/0111647).

Regarding Claim 19, Latson teaches an expansible device for use in a body lumen or tract, the device comprising: a tubular member (7) having a proximal end and a distal end; a first expansible member (distal end of frame 9) disposed on the distal end of the tubular member, the first expansible member having a contracted configuration (fig. 3) and an expanded configuration (fig. 6), wherein the first expansible member comprises a wire (9) that can be shifted between an elongate contracted configuration and a helical expanded configuration (Fig. 6 is helix, Fig. 5 is contracted); a first deformable membrane (6) at least partially disposed over the first expansible member in the expanded configuration; a second expansible member (proximal end of frame 9) disposed proximal the first expansible member on a distal end of the tubular member, the second expansible member having a contracted configuration (fig. 3) and an expanded configuration (fig. 6).

Latson does not specify wherein the first deformable membrane has a spherical shape when the first expansible member is in the expanded configuration and the second expansible member has a cylindrical shape in the expanded configuration. Latson does however say the bag is preferably disc shaped, however the term preferably means there are other options for the shape of the expansible member

(Latson, col. 3, ll. 6). Khairkhahan teaches a spherical shape when expanded (Figs. – 10). It would have been obvious to one of ordinary skill in the art to use the shape of Khairkhahan with the device of Latson as the spherical shape may be preferable in different applications, as the front face would be rounded instead of flat, making the entry of the device into a certain body part smoother. The sphere of Khairkhahan is structurally stonger than the disc of Latson, because the stress concentration is evenly distributed in a sphere.

Regarding Claim 22, Latson teaches the device of claim 20, wherein the second expansible member comprises a coil or spring of wire (9).

Regarding Claim 23, Latson fails to disclose the diameter of the coil wire. Khairkhahan teaches a device for occluding an opening, wherein the second expansible member is of a diameter .19 inches. It would have been an obvious matter of design choice to disclose the diameter of the coil and wire as being within the disclosed range since it appears that the device of Latson performs the task of closing a hole in tissue equally well as that of the disclosed application, and it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding Claim 24, Latson teaches the device of claim 22, further comprising a second deformable membrane (5) at least partially disposed over the second expansible member in the expanded configuration (fig. 6).

Regarding Claim 25, Latson teaches the device of claim 24, further comprising ribs on a surface of the second deformable membrane (col. 4, ll. 36,37).

Claims 19, 21, 29, 30 and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brenneman et al. (US 6071300) in view of Kensey (US 5061274).

Brenneman teaches a method of sealing a puncture site comprising the following: providing an expansible device having a tubular member (20), a first expansible member (50) disposed on a distal end of the tubular member (20) wherein the first expansible member comprises a wire (82) that can be shifted between a straight contracted configuration and a helical expanded configuration (having the form of a spiral includes a curve formed about the axis, a partial helix is shown in Fig. 4A); and a second expansible member (42) disposed proximal the first expansible member on the distal end of the tubular member; inserting the expansible device in the puncture site (fig. 1a); deploying the first expansible member to an expanded configuration comprising a spherical shape (fig. 1b); deploying the second expansible member to an expanded configuration comprising a cylindrical shape (fig. 7).

- wherein the first and second expansible members (50,42) are deployed sequentially (figs. 1a-1c, fig. 1).
- wherein the first expansible member is deployed against a blood vessel wall (fig. 1).
- wherein the second expansible member is deployed against a tissue tract (fig. 1).
- wherein deploying the second expansible member comprises inflating the second expansible (42) member with a predetermined volume of air (fig. 1c to fig. 5).

Brenneman fails to teach wherein the first expansible member comprises a first deformable membrane at least partially disposed over the first expansible member in an

expanded configuration. Kensey teaches a method for sealing a puncture site, wherein the expansible member (20) is covered with a non-thrombogenic waxy membrane in order to minimize the risk of thrombosis. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Brenneman with a membrane on the first expansible member as taught by Kensey in order to minimize the risk of thrombosis.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Brenneman and Kensey as applied to claim 29 above, and further as a matter of design choice. The combination of Brenneman and Kensey teaches all limitations of dependent claim 29, and further teaches wherein wherein the first and second expansible members are deployed sequentially, but fails to teach wherein the first and second expansible members are deployed simultaneously. It would have been an obvious matter of design choice to modify the method of Brennemen by simultaneously deploying the first and second expansible members, since the combination of Brenneman and Kensey is capable of performing that function, and in paragraph 79 of the present application, applicant asserts that it is preferable to deploy the first and second members sequentially, and it appears that the method of the combination of Brenneman and Kensey performs the task of sealing a puncture equally well as that of the present application.

***Response to Arguments***



The arguments regarding the 102(b) rejection using Marino has been persuasive.

Applicant's arguments filed 1/29/08 have been fully considered but they are not persuasive. The applicant generally argues:

- Latson fails to teach the geometries
- Khaikhahan fails to teach a wire with a helical expanded configuration
- Neither Brenneman or Kensey teach an elongate contracted configuration and a helical expanded configuration

The examiner agrees with the applicant, Latson fails to teach the geometries, however the geometries are taught by Khaikhahan as described in the above rejection. As explained above Khaikhahan teaches a portion of the wire has a helical shape, as the claim does not state forming a complete helix the examiner uses the broadest reasonable interpretation of the term helical, which Khaikhahan does indeed teach. Brenneman teaches an elongate contracted configuration (164, Fig. 9 the wire is straight) and a helical expanded configuration (Fig. 5, the wire is in a partial helical configuration).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Ryckman whose telephone number is (571)-272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/  
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